For our Environment

Umwelt Bundesamt

Fluoros 2015 – Risk Assessment and Regulatory Policy

Assessment and Regulatory Approaches in Europe

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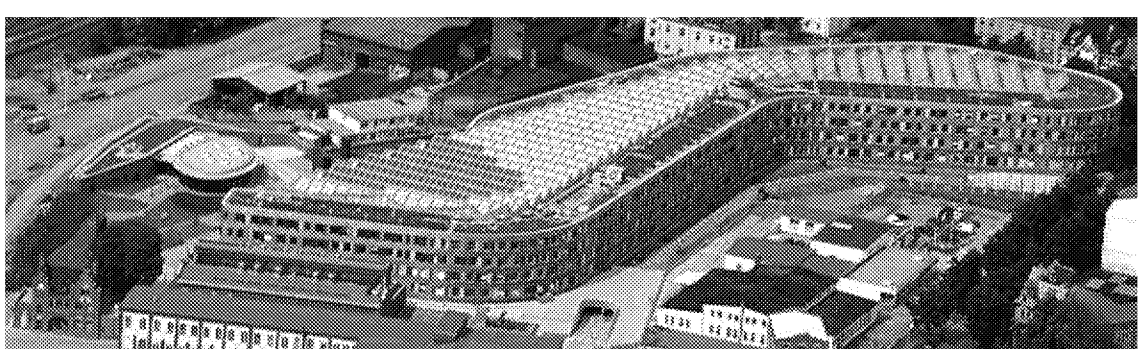
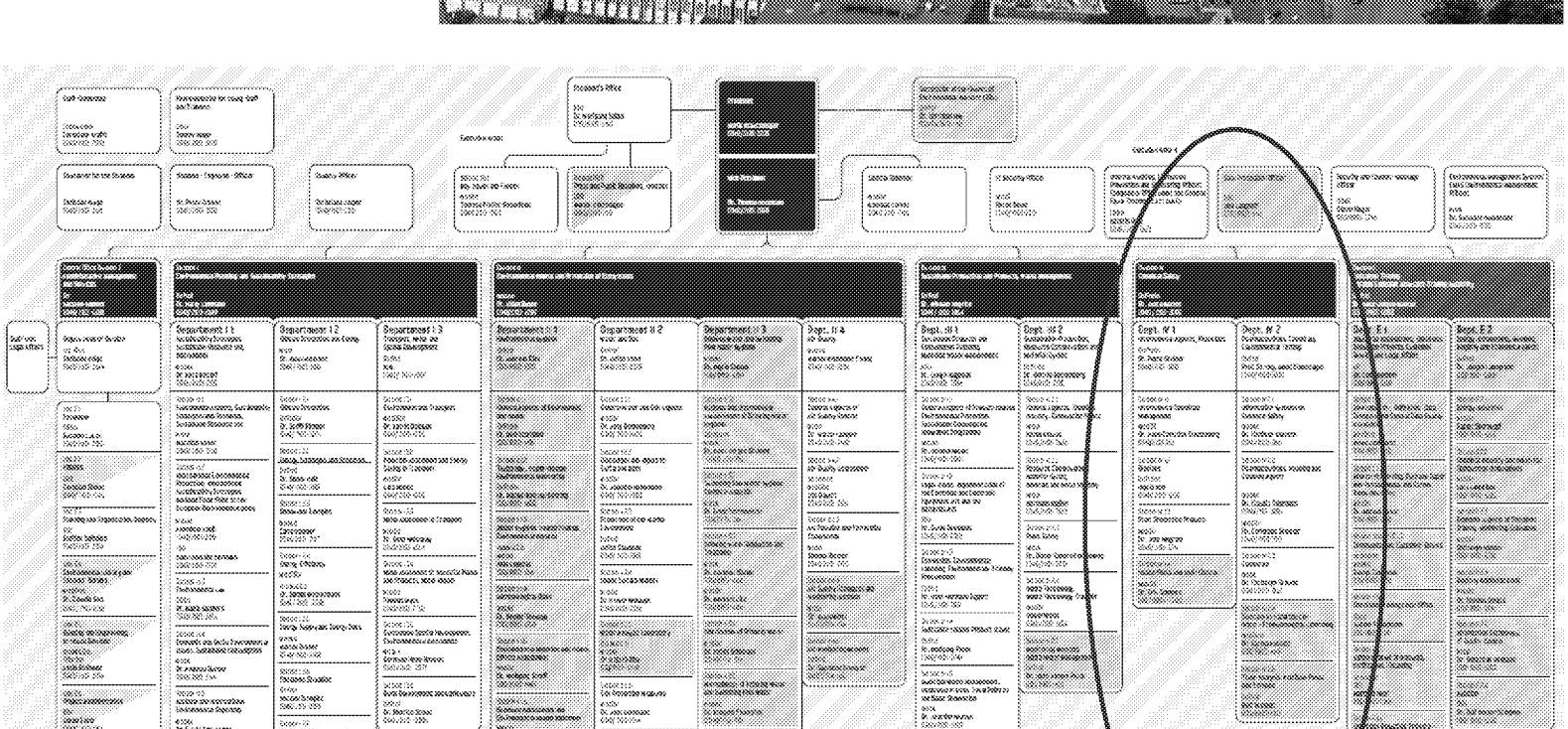
Section IV 2.3 Chemicals
Federal Environment Agency (UBA)
Germany

UBA



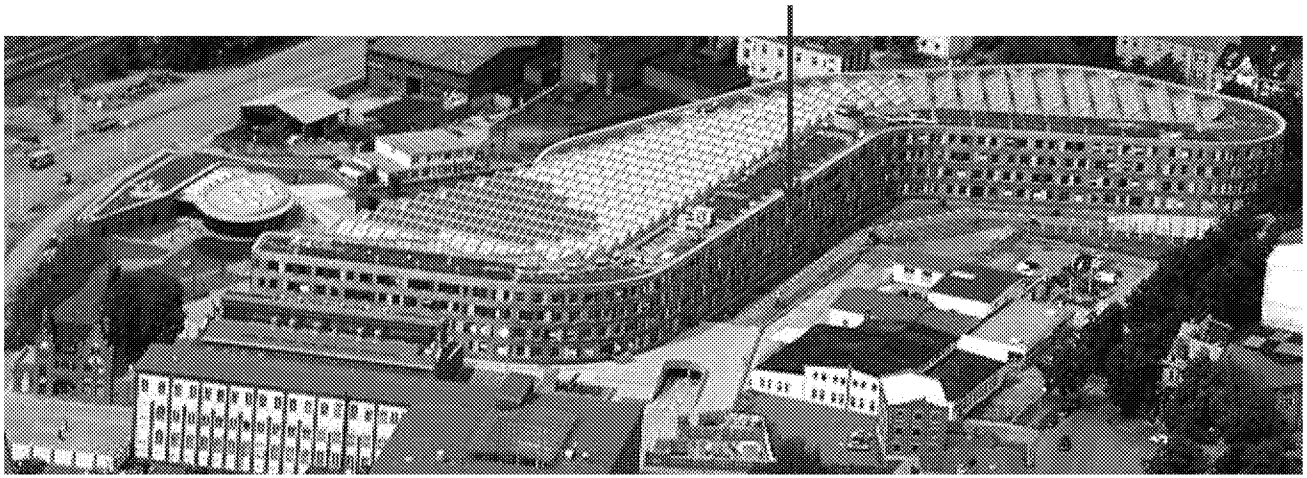
Umwelt Bundesamt

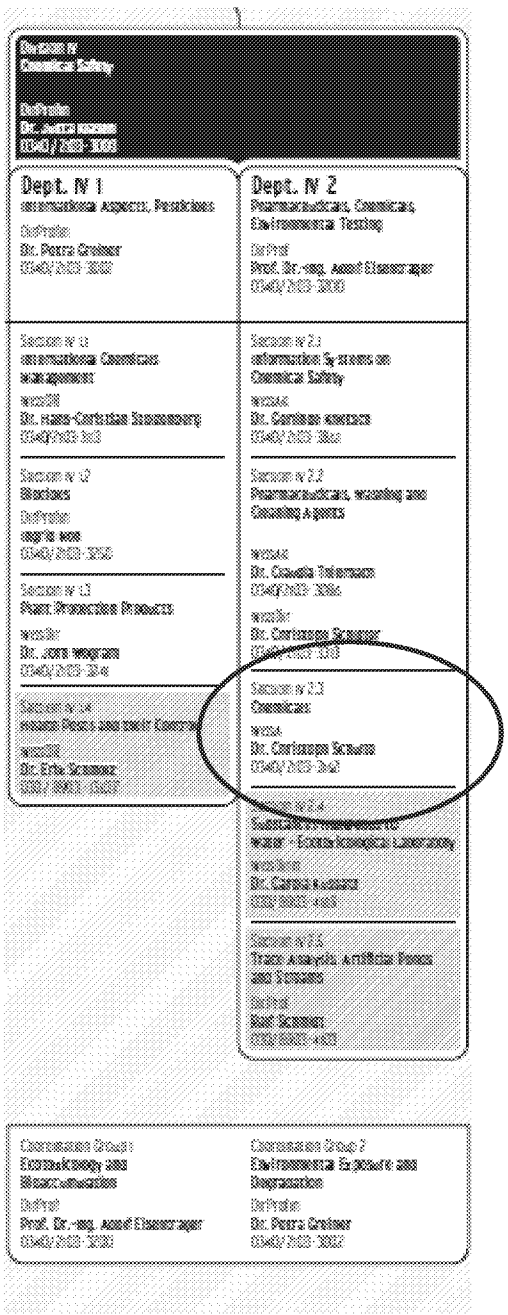


UBA

Mission of Germany's Federal Environment Agency
"For our environment" ("Für Mensch und Umwelt")

Main Task: to ensure that citizens have a healthy environment where they are protected against air, water and other pollutants





PFAS - Main concerns

1. Environmental persistence
2. Findings and distribution in surface water
3. Findings and accumulation in food webs and top predators
4. Long-range transport and findings in remote areas
5. Occurrence in blood samples and breast milk of the general population (& long elimination half lives)
6. Findings in food and (increasingly) drinking water
7. Toxicological profile (PFOS, PFNA, PFOA: Reprotoxic Cat. 1B)

Short-chain PFAS

- **Persistent chemicals with high mobility in the (aqueous) environment**
- Potential for transport over long distances
- Potential to reach remote regions
- Accumulation in the environment
- Potential to reach ground water as a resource for drinking water
- Difficult to remediate (lower adsorption)

Objectives for managing PFAS

PFAS are

- ubiquitously present in the environment
- substances of (very high) concern
- manufactured and processed worldwide
- released from fluoropolymer and fluorinated polymer manufacturing or processing facilities, wastewater treatment plants and landfill all over the world
- present as residuals or impurities in fluoropolymers and fluorinated polymers used for a variety of (imported) (consumer) products

=> Need for global management

Regulatory Activities

2pp

3M News

AR226-0641

3M Home Page News and Profile Press Box

FOR IMMEDIATE RELEASE

3M Phasing Out Some of its Specialty Materials

ST. PAUL, Minnesota – May 16, 2000 – 3M today announced it is phasing out of the perfluorooctanyl chemistry used to produce certain repellents and surfactant products.

The affected product lines represent about two percent of 3M's nearly $16 billion in annual sales. These include many Scotchgard products, such as soil, oil and water repellent products; coatings used for oil and grease resistance on paper packaging; fire-fighting foams; and specialty components for other products. 3M said it plans to substantially phase out production by the end of the year and will work with customers to accomplish a smooth transition. "Our decision anticipates increasing attention to the appropriate use and management of persistent materials," said Dr. Charles Reich, executive vice president, Specialty Material Markets. "While this chemistry has been used effectively for more than 40 years and our products are safe, our decision to phase out production is based on our principles of responsible environmental management."

"We're reallocating resources to accelerate innovation in more sustainable opportunities and technologies. This decision is not only in the public interest, it's in the best interests of all our constituencies … our employees, customers, communities and investors," Reich said.

Sophisticated testing capabilities – some developed in only the last few years – show that this persistent compound, like other materials in the environment, can be detected broadly at extremely low levels in the environment and in people. All existing scientific knowledge indicates that the presence of these materials at these very low levels does not pose a human health or environmental risk. 3M expects to meet consensus earnings estimates for the rest of 2000. This excludes a one-time charge on the order of $200 million, that will be taken sometime this year.

Regulatory activities for PFAS worldwide

2000 Announcement of 3M to phase out **PFOS**

2006 US-EPA Stewardship program: Reduce emissions of **PFOA** and precursors to 95% of the level of 2000 till 2010, phase out till 2015, also for longer chain PFCAs and precursors

2006 EU-Restriction for **PFOS**, obligation to assess also PFOA

2008 OECD Hazard Assessment for **PFOA** prepared by US-EPA and UBA, supported by DuPont: candidate for further work

2009 **PFOS** added to Annex of Stockholm Convention

2013 **PFOS** and derivates included in Annex X of the European Water Framework Directive as Priority Hazardous Substance

Environmental Quality Standards for PFOS

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
No	Name of substance	CAS number (a)	AA-EQS (b) Inland surface waters (c)	AA-EQS (b) Other surface waters	MAC-EQS (d) Inland surface waters (c)	MAC-EQS (d) Other surface waters	EQS Biota (e)
(35)	Perfluorooctane sulfonic acid and its derivatives (PFOS)	1763-23-1	$6{,}5 \times 10^{-4}$	$1{,}3 \times 10^{-4}$	36	7,2	9,1

REACH

30.12.2006 EN Official Journal of the European Union

I

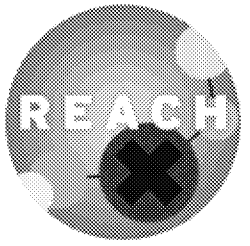
(Acts whose publication is obligatory)

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

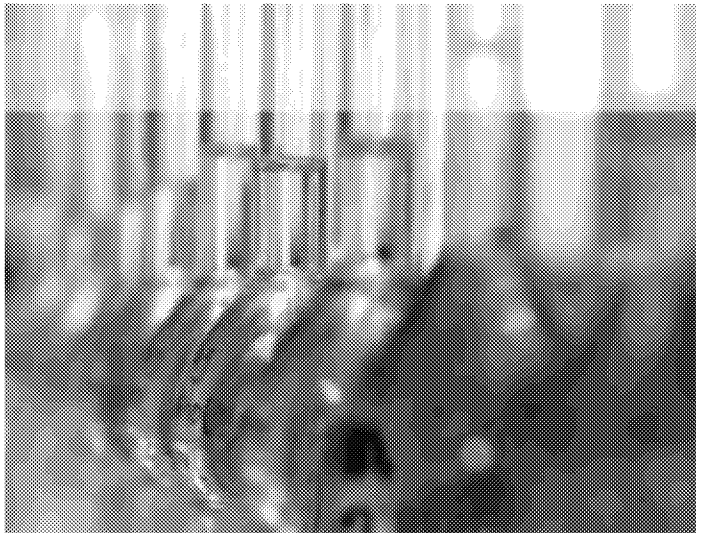
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93

REACH



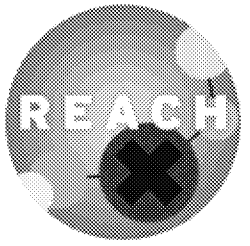
- One legislation for new and existing chemicals, replacing a set of chemical regulations in the EU
- No data - no market: Registration of all chemicals manufactured or imported >1 metric ton/a
- Manufacturers, importers and downstream users need to ensure that they manufacture, place on the market or use only such substances that do not adversely affect human health or the environment
- Responsibility of enterprises of the chemical industry to manage risks and to provide information on (safe) uses of chemicals

REACH - objectives



- Ensure a high level of protection of human health and the environment
- Use chemicals safely through the product-chain and the complete life-cycle
- Ensure the free circulation of substances on the market
- Enhance competitiveness and innovation
- Promote the development of alternative methods for the assessment of hazards of substances
- Promote sustainable development

REACH – Main instruments

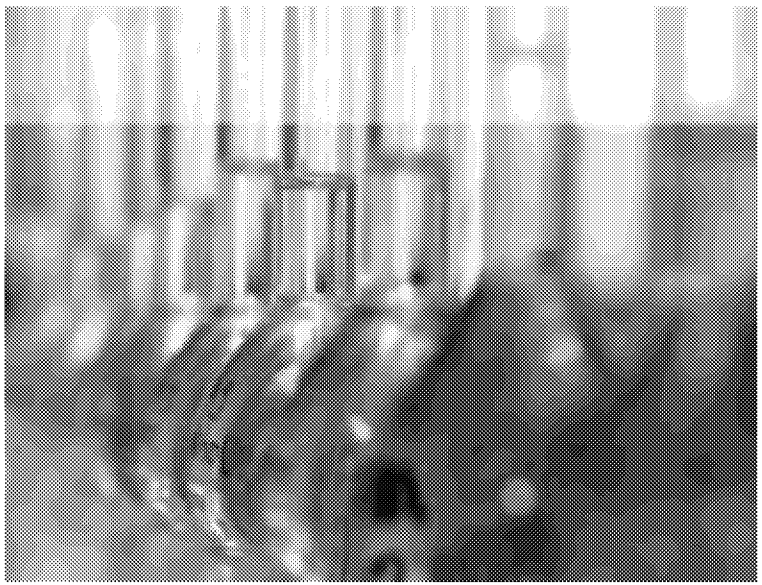


- **Registration** needs to assess all available information, hazards and risks
- With a registration, companies proof the safe use for the whole life-cycle of a substance
- **Evaluation** is task of the authorities to verify the quality of registrations and assessment
- At least 5% of all registered dossiers need to be checked for compliance by the European Chemicals Agency (ECHA)
- Member States select certain substances for substance evaluation, and nominate them for the community rolling action plan (CoRAP)

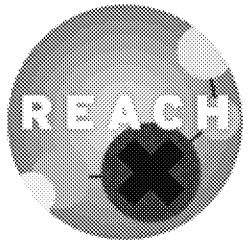
REACH – Substances of Very High Concern (SVHC)

Article 55

„ ... assuring that the risks from **Substances of Very High Concern** are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable..“



REACH – Substances of Very High Concern (SVHC)



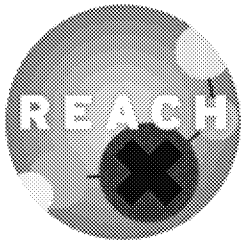
.. meeting the criteria as CMR category 1A or 1B

.. are **persistent, bioaccumulative** and **toxic** in accordance with the criteria set out in Annex XIII (PBT-Substances)

.. are **very persistent** and **very bioaccumulative** in accordance with the criteria set out in Annex XIII (vPvB-Substances)

.. having endocrine disrupting or PBT or vPvB properties (but not fulfilling the criteria) for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern

REACH – Regulatory instruments



1. Candidate List

- Substances for eventual inclusion in Annex XIV
- EU-wide agreement on SVHC-Status
  (no C&L for PBT, vPvB and ED)
- Need for EU-wide regulatory action to minimise exposure of men and environment
- Motivation for producers, users, and suppliers to establish substitutes or at least minimise exposure (self-responsibility)
- Give consumers the opportunity to ask retailers for SVHC in articles (and to influence the market)
- Promote substitution (& never come back …)

Candidate list

ECHA
EUROPEAN CHEMICALS AGENCY

About Us | Regulations | Addressing Chemicals of Concern | Information on Chemicals | Chemicals in our Life | Support

ECHA > Addressing Chemicals of Concern > Authorisation > Substances of very high concern identification > Candidate List of Substances of Very High Concern for Authorisation > Candidate List table

Candidate List of Substances of Very High Concern for Authorisation

(published in accordance with Article 59(10) of the REACH Regulation)

Substance Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number	IUCLID 5 Substance Dataset	
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	2013/06/20	Toxic for reproduction (Article 57 c); PBT (Article 57 d)	ED/69/2013		Details
4-Nonylphenol, branched and linear, ethoxylated *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]*	-	-	2013/06/20	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	ED/69/2013		Details
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	2013/06/20	Toxic for reproduction (Article 57 c); PBT (Article 57 d)	ED/69/2013		Details

http://echa.europa.eu/de/candidate-list-table

REACH – Regulatory instruments

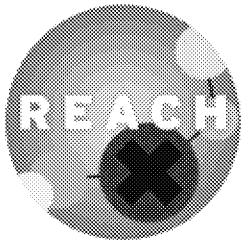
2. Authorization

- Substances of Very High Concern (SVHC)
- Prerequisite: Listed in Annex XIV of Regulation
- Only authorized uses are allowed
- Authorization may be granted, if
    - Risk is adequately controlled,

    or

    - Socio-economic benefits outweight the risk and no substitutions or alternatives are available

REACH – Regulatory instruments



3. Restriction

- Substances with unacceptable risk to health or the environment
- May also an appropriate measure for SVHC
- All uses which are not specifically restricted are allowed
- Any use or import of substance is regulated by conditions of restriction
- Could also address maximum residue levels in articles
- Might include relevant precursors
- Appropriate to regulate substances in articles

UBA-strategy to manage PFAS

1. Regulatory approaches
2. Stakeholder dialoque
3. Information and awareness raising

Regulatory approaches

- Regulatory activities must include all substances contributing to PFCAs and PFSAs as stable degradation products
- Identify long chain PFAS as SVHC due to PBT/vPvB properties
- Restrict manufacture, use and import of **PFOA and precursors**
- Restrict manufacture, use and import of **long-chain PFAS and precursors**
- Assess **short-chain PFAS** using REACH substance evaluation

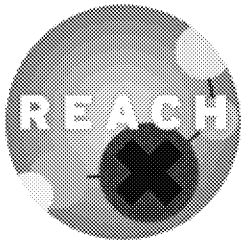
Regulatory activities for PFAS under EU CLP-Regulation

2013 **PFOA** is included in Annex VI of CLP-regulation as toxic for reproduction category 1B

2014 Proposal for harmonised classification and labeling of **PFNA** as toxic for reproduction category 1B supported by responsible Scientific Body (Risk Assessment Committee – RAC)

2014 Proposal for harmonised classification and labeling of **PFDA** as toxic for reproduction category 1B submitted to ECHA

Regulatory activities for PFAS under REACH



2012 **C11-C14 PFCAs** are identified as vPvB-Substances, and included as Substances of Very High Concern (SVHC) in Candidate List

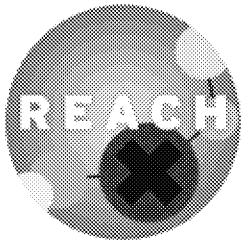
2013 **PFOA** is identified as CMR- and persistent, bioaccumulative and toxic (PBT) Substance and included as SVHC in Candidate List

2014 Restriction proposal **for PFOA and Precursors** submitted by Germany and Norway

2015 Sweden and Germany propose to identify **PFNA** as CMR and PBT-Substance for inclusion in Candidate List

2016 Sweden and Germany intend to propose to identify **PFDA** as CMR and PBT-Substance for inclusion in Candidate List

Regulatory activities for PFAS under REACH



2013 Substance evaluation for

- Ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly (substituted alkene)] phosphate
- Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt

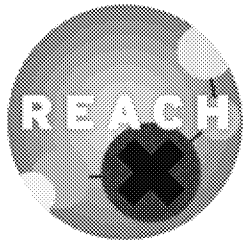
2013 ECHA established PFAS-group to co-ordinate activities of Member States and develop an assessment strategy

2016 Substance evaluation for

- 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate
- 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate

http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Regulatory activities for PFAS under REACH

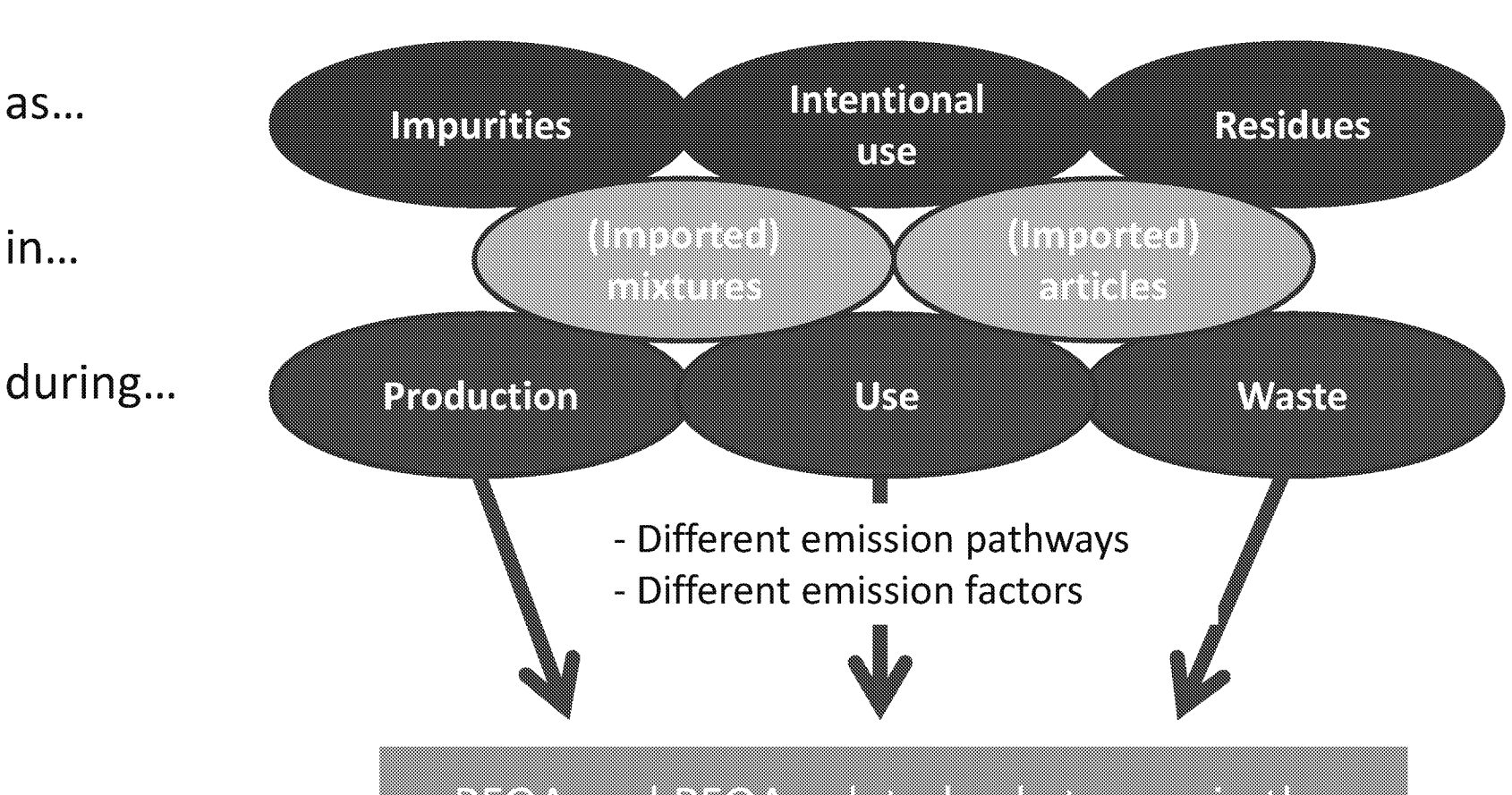


2017 Substance evaluation for

- 2-[methyl[(nonafluorobutyl) sulpho-nyl]amino]ethyl acrylate
- ammonium 2,2,3 trifluor-3-(1,1,2,2,3,3-hexafluoro-3-trifluormethoxypropoxy), propionate,
- ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate
- ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate
- bis(nonafluorobutyl) phosphinic acid
- polyfluoro-5,8,11,14-tetrakis(polyfluoralkyl)-polyoxaalkane
- trade name: wässrige Lösung des MV 31-Kaliumsalzes

http://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

PFOA, its salts, and PFOA-related substances



Restriction proposal

PFOA including its salts, and any other substance having linear or branched perfluoroheptyl derivatives with the formula C7F15- as a structural element, including its salts

1. Shall not be manufactured, used or placed on the market
   - as substances,
   - as constituents of other substances in concentrations equal or above 2 ppb of a single substance,
   - in a mixture in concentrations equal or above 2 ppb of a single substance
2. Articles or any parts thereof containing one of the substances in concentrations equal to or greater than 2 ppb of a single substance shall not be placed on the market.

http://www.echa.europa.eu/restrictions-under-consideration

UBA-strategy to manage PFAS

1. Regulatory approaches
2. Stakeholder dialoque
3. Information and awareness raising

Stakeholder dialogue

Case: PFAS in fire fighting foams

- PFAS are used in fire fighting foams since the 1960s („Light water“ – PFOS-based)
- Point sources with high environmental exposure
- High potential for contamination of soil, surface water, and ground water
- PFAS-containing fire fighting foams are often not the appropriate choice

Approach: Dialogue with stakeholders in Germany

Stakeholder dialogue

Open discussions between UBA, german fire fighting associations, security associations, and foam manufacturers on high level

Results:

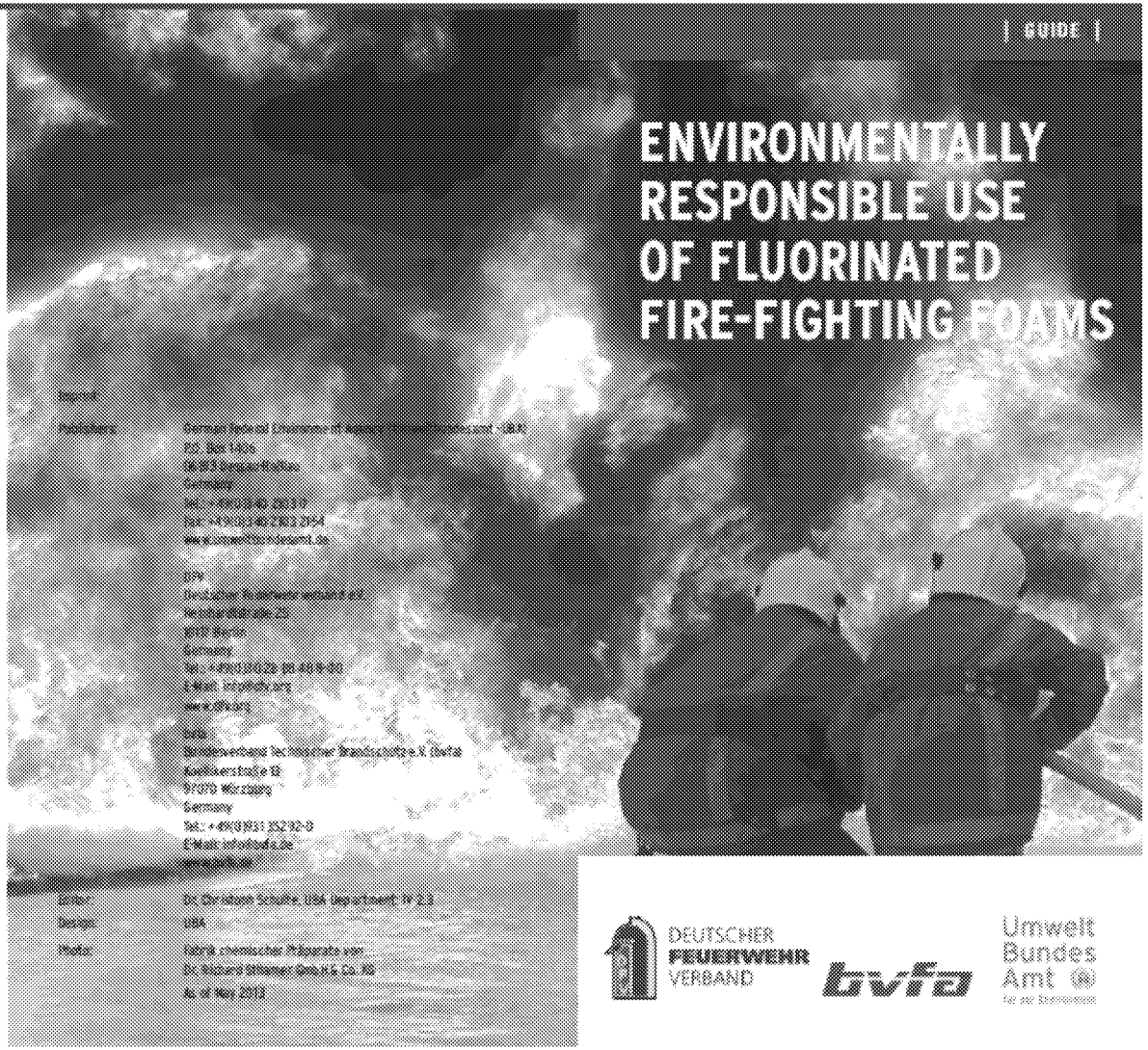
- Several joint publications in fire fighting journals
- Flyer for fire fighters
- Public discussions on conferences for fire protection and prevention
- ….

Stakeholder dialogue

8. **How should released fluorinated fire-fighting foams be dealt with?**

The environment, and particularly water pollution control, sets high standards for the use of fluorinated fire-fighting foams.

Their use should be limited as much as possible to mobile operations, run off water should be recollected (e.g. by suction vehicle or absorbents) and appropriately disposed of. In cases of doubt, necessary measures should be coordinated with the local environment office. In the case of fixed fire-fighting systems, appropriate extinguishing water retention systems should be planned and employed.



UBA-strategy to manage PFAS

1. Regulatory approaches
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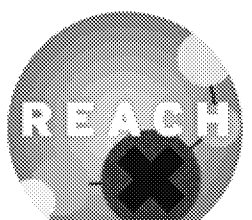
3. Information and awareness raising

Information and awareness-raising



Start | Das UBA | Themen | Presse | Publikationen | Daten

› Presse ›
Presseinformationen › REACH: EU bestätigt besonders besorgniserregende Eigenschaften für Chemikalie in...

REACH: EU bestätigt besonders besorgniserregende Eigenschaften für Chemikalie in Outdoorkleidung

Verbraucher müssen über REACH-Kandidaten Auskunft erhalten

Die REACH-Kandidatenliste umfasst jetzt 144 besonders besorgniserregende Chemikalien. Deutschland hatte auf Initiative des Umweltbundesamtes (UBA) die Aufnahme von sieben besonders umweltgefährlichen Chemikalien vorgeschlagen. Darunter ist die Perfluoroktansäure (PFOA), die sich oft in wetterfesten und wasserresistenten Textilien wiederfindet. Sie gilt seit langem als umweltschädlich. Jochen Flasbarth, Präsident des Umweltbundesamtes: „Besonders besorgniserregende Chemikalien gehören nicht in die Umwelt und sollten auch in Verbraucherprodukten ersetzt werden. Durch die Aufnahme eines Stoffes in die REACH-Kandidatenliste erhalten Verbraucherinnen und Verbraucher besondere Auskunftsrechte, von denen sie auch Gebrauch machen sollten." Am einfachsten geht das mit der Online-Anfrage unter www.reach-info.de. Insgesamt sind nun fast 12.000 Chemikalien in der EU registriert. Ein Großteil der Registrierungen stammt aus Deutschland.

24.06.2013 ★ 22 mal als hilfreich bewertet Nr. 26/2013

Die EU-Mitgliedstaaten bestätigten den gemeinsamen Vorschlag aus

Links

Aktuelle Liste besonders

Presse

- Presseinformationen
- Presseanfrage
- Pressekontakt
- Pressetermine
- Das UBA in Presse & Öffentlichkeit

Presseinformationen abonnieren

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Information and awareness-raising

http://www.umweltbundesamt.de/themen/pfc-planet-chemikalien-sind-ueberall

Global Activities – OECD, UNEP, and SAICM

OECD

2006 OECD/KEMI - Workshop on perfluorocarboxylic acids Stockholm

2008 Hazard assessment for PFOA, prepared by US-EPA and German UBA, supported by DuPont: **candidate for further work**

Established PFC Steering group

- Collect more reliable data on use and production of PFCs
- Surveys on production, use and releases to the environment
- *PFC-Portal: http://www.oecd.org/ehs/pfc/*

SAICM

ICCM 2: Resolution II/5 invited relevant stakeholders to promote PFC stewardship programmes and to contribute to:

- Information-gathering activities, such as the OECD survey;
- Information exchange on alternatives currently in use, including short chain-length fluorocarbons, and potentially safer alternative substances or technologies for their use; ..

ICCM 3: Resolution adopted

- Welcomes efforts to date and states much remains to be done
- Takes note of establishment of Global PFC Group
- Invites OECD and UNEP to carry on and report progress to ICCM4
- Requests close cooperation with Stockholm convention and UNIDO

ICCM 4: Progress Report, side event will be organised

The global PFC Group

- Mandate: Establish a global group, given importance of countries outside OECD region in production and use of PFCs
- UNEP and OECD serve as secretariat
- Open and informal group that operates through conference calls:
- Developing countries and emerging economies are regular participants to the Group
- Participants: Russia, China, India, Brazil, Cuba, Benin, Pakistan, Japan, Canada, USA, Germany, Netherlands, Sweden, Norway, Australia, Korea, Chile, Italy, Czech Republic, Switzerland, European Commission, SETAC, Fluorocouncil

Work programme 2012- 2015

Key activities - endorsed by ICCM 3

:**PFC Web Portal**, regular updates, *http://www.oecd.org/ehs/pfc/*

1. **Synthesis papers** on scientific evidence, regulatory approaches, alternatives to long-chain PFAS
2. **Webinars and other events**: focus on the topics of the synthesis papers
3. **PFC survey:** Reach out to main PFC producers; agree on survey methodology in expert workshop; implement survey; publish survey
4. **Information about uses** of PFCs
5. **Cooperation** with the Stockholm Convention and UNIDO

Webinars and Publications

Webinars 2013 /2014:

1. Overview of PFCs Landscape
   – Key issues and insights
2. Major uses of PFCs and scientific evidence
3. Recent developments in alternatives to long chain PFCs
4. Regulatory approaches

Papers on Risk reduction approaches and global emission inventories in preparation:

http://www.oecd.org/ehs/pfc/pfceventsmeetingswebinars.htm

Summary

1. The world-wide distribution of PFAS is leading to long-term and global exposure of ecosystems and the population
2. Sources are complex, and include precursors, degradation products and residues in articles
3. Regulatory activities must include all substances contributing to PFCAs and PFSAs as stable degradation products
4. Production and use are expanding globally, hence risk management approaches need to be harmonised globally as initiated by OECD, UNEP, and others
5. The scope of the risk management activities needs to be expanded from long chain PFAS to include also short chain PFAS

Thank you for your attention!

Dr. Christoph Schulte
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